



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,996	03/11/2004	Lixiao Wang	S63.2-7182-US02	6285
499 7590 05/09/2008 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344				
EXAMINER				
DANIELS, MATTHEW J				
ART UNIT		PAPER NUMBER		
1791				
MAIL DATE		DELIVERY MODE		
05/09/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/797,996
Filing Date: March 11, 2004
Appellant(s): WANG ET AL.

Lisa Ryan-Lindquist
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 26 February 2008 appealing from the Office action mailed 16 July 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The amendment after final rejection filed on 12 September 2007 has been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,843,116	CROCKER ET AL.	12-1998
3,953,566	GORE	4-1976

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 18 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crocker (USPN 5843116) in view of Gore (USPN 3953566).

As to Claim 18, Crocker teaches a method of forming the balloon comprising the steps of:

- i) providing first (Fig. 3, item 36), second (Fig. 3, items 40 and 44) and third tubes (Fig. 3, item 38);
- ii) inserting the first tube into the second tube (Fig. 3, items 40 and 44);
- iii) inserting the second tube into the third tube (Fig. 3);
- iv) inserting the first, second and third tubes into a balloon mold (7:35-50);
- v) expanding the first, second and third tubes at a desired temperature so as to form a balloon (7:35-50, particularly 7:37-40).

Crocker appears to be silent to the second tube formed of a tube made of a material selected from the group consisting of fluoropolymers and high density polyethylene. However, Crocker clearly suggests cross-linked polyethylene (5:35-39).

Additionally, Gore teaches a PTFE (a fluoropolymer) tubular product (14:17-20) having a porous or dense structure and extremely high strength which would have been suitable for use in Crocker's method as the expansion limiting bands (Crocker, 5:28-30). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Gore into that of Crocker because:

- a) Crocker provides a lamination process (7:8-62), and Gore suggests that the PTFE material is useful in laminated structures (1:39-40).

Art Unit: 1791

b) The extremely high strength product of Gore (1:30) would be desirable to Crocker in order to provide the suggested structural integrity and limited expansion of the balloon (5:46-52).

As to Claim 23, Crocker teaches a method of forming a balloon comprising the steps of:

- i) providing first (Fig. 3, item 36), second (Fig. 3, Items 40 and 44) and third (Fig. 3, Item 38) tubes,
- ii) inserting the first tube into the second tube (Fig. 3);
- iii) inserting the second tube into the third tube (Fig. 3);
- iv) laminating the first tube and the second tube together (7:8-62);
- v) laminating the second tube and third tube together so as to form at least a three tube laminate (7:8-62).

Crocker is silent to the second tube formed of expanded PTFE. However, Gore teaches a PTFE (a fluoropolymer) tubular product (14:17-20)) having a porous or dense structure and extremely high strength which would have been suitable for use in Crocker's method as the expansion limiting bands (Crocker, 5:28-30). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate the method of Gore into that of Crocker because:

- a) Crocker provides a lamination process (7:8-62), and Gore suggests that the PTFE material is useful in laminated structures (1:39-40).
- b) The extremely high strength product of Gore (1:30) would be desirable to Crocker in order to provide the suggested structural integrity and limited expansion of the balloon (5:46-52).

As to Claim 24, Crocker provides first and third tubes laminated together at least in part (7:40-50). **As to Claim 25**, in the invention of Crocker the temperature was predetermined

(7:40-50). **As to Claim 26**, Crocker teaches that while items 36, 40, and 38 may be bonded together (7:8-11), it is possible to attach the components without adhesively bonding or securing the two balloons together or in a configuration where the expansion limiting bands are merely sandwiched (7:23-25, 7:50-65) between the balloons. In either embodiment, subsequent expansion of the balloon would cause delamination of the first and second tubes and the second and third tubes upon blowing the balloon either by expanding the adhesively bonded areas or separating the unbonded areas.

(10) Response to Argument

Appellants' Argument:

Appellants argue that cross-linked polyethylene disclosed by Crocker is different than high density polyethylene (Supp. Br. 4). Appellants further argue that cross-linked polyethylene is a polyethylene that has been subsequently modified by linking its molecules, and is a distinctly different class of polymer materials no readily substitutes for one another (*Id.*). Appellants further argue that simply using the term "high density polyethylene" is enough to differentiate the material not only from the thermoset polyethylene of Crocker, but from other types of known thermoplastics such as "low density", "linear low density", "medium density", and "crosslinked" polyethylene (Supp. Br. 5). Appellants further argue that the Gregorian reference produces a crosslinked high density polyethylene, but any person of skill in the art recognizes that the crosslinked high density polyethylene material is no longer the same as "high density polyethylene" (Supp. Br. 5-6).

Response

The main issue in this case appears to be whether it would have been obvious to one of ordinary skill in the art to use a high density polyethylene or expanded polytetrafluoroethylene material as the non-distensible bands of Crocker. The non-distensible bands of Crocker are shown as items 40 and 44 in Fig. 2.

Since both independent claims would be met by the substitution of an expanded polytetrafluoroethylene material (which is a fluoropolymer) for the non-distensible bands of Crocker, if the combination of Gore and Crocker set forth in the rejections of Claims 18 and 23 above is found to be obvious, it would be unnecessary to reach any decision regarding the alternative high density polyethylene material recited in Claim 18.

In the alternative, however, it is submitted that substitution of a high density polyethylene for the material of Crocker would have nevertheless been obvious. In *KSR International Co. v. Teleflex*, the court cited with approval the decision of *United States v. Adams* by stating "[t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *KSR International Co. v. Teleflex*, 82 USPQ2d 1385, 1395 (citing *United States v. Adams*, 383 U.S., at 50-51). "[T]he analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 82 USPQ2d at 1389. The Examiner submits in this case that Crocker's teaching of "polyethylene" (col. 5, line 38) in combination with the inferences and knowledge

employed by the ordinary artisan render this claim obvious because one would have selected the appropriate type of polyethylene material.

The term “polyethylene” as used by Crocker appears to be a generic term encompassing a number of notoriously well known polyethylenes, and one of ordinary skill in the art would have selected a suitable polyethylene to fulfill the claimed use. The claimed high density polyethylene is a conventionally known thermoplastic material (Supp. Br. 6) which has already been used in balloon catheters (Spec. 6, line 19 incorporates by reference US 5447497, and this teaching is found at col. 2, ll. 28-40 of US 5447497). Thus, because Crocker expressly teaches polyethylene and because high density polyethylene is conceded by the specification to be a conventional material known for use in balloon catheters, the use of high density polyethylene as the non-distensible bands of Crocker (40, 44) would have been obvious. The claim appears to recite no more than a substitution of a particular, but conventional, type of polyethylene into a process which expressly suggests polyethylene.

The Examiner submits that little weight should be given to the argument that “high density polyethylene” is limited solely to thermoplastic polymers (Supp. Br. 5-6). The argument is not commensurate with the scope of the claim which does not exclude crosslinked polymers or require thermoplastic polymers. The argument also rests on extrinsic evidence which shows merely that HDPE can be provided in a thermoplastic form, but there is no reason to believe that either (a) subsequent crosslinking is precluded in such a material, or (b) if crosslinking of a high density polyethylene did occur, it would lose its character as a “high density polyethylene.”

Art Unit: 1791

Appellants' Argument:

With respect to the combination of Crocker with the Gore reference, Appellants argue that it is incorrect to state that the PTFE product of Gore has a dense structure (Supp. Br. 6-7). Appellants further argue that nothing would lead one skilled in the art to substitute the PTFE of Gore for the expansion limiting bands (40, 44) of Crocker because Crocker does not suggest PTFE (Supp. Br. 7). Appellants also argue that Gore fails to describe the specific PTFE material employed therein as being either inelastic or nondistensible (*Id.*). Appellants further argue that Gore provides no basis for selecting PTFE and one of ordinary skill in the art would not be led to conclude that the PTFE tube of Gore would indeed be a substitute for the expansion limiting bands of Crocker (Supp. Br. 8).

Response:

As a preliminary matter, Appellants argue that it is incorrect to state that the PTFE product of Gore has a dense structure. However, Gore states: "Also, dense products of polytetrafluoroethylene are produced that have extremely high strengths. These and other objective appear hereinafter." (col. 1, ll. 29-31). Both porous and dense PTFE polymers are therefore objectives within the scope of the Gore disclosure. Nevertheless, all independent claims are met by the expanded PTFE of Gore in combination with the process disclosed by Crocker.

The Examiner maintains the position that one of ordinary skill would have recognized the material of Gore as a material that could be substituted for the material of the expansion limiting bands of Crocker. First, Gore teaches that during the expansion process a tremendous (greater

Art Unit: 1791

than tenfold) increase in strength is introduced into the structure (col. 3, ll. 4-8), producing the porous (expanded) polytetrafluoroethylene. This suggests that the material is nondistensible and high strength, and one of ordinary skill in the art at the time of the invention would have recognized its utility as a substitute for the other materials already disclosed by Crocker (col. 5, ll. 28-39). Appellants have not pointed to or presented any evidence of particular difficulty or unexpected results in making the claimed combination. Therefore, the fact that this invention substitutes one known material (Gore) for another (Crocker) which does no more than obtain predictable results supports the conclusion that the invention would have been obvious. While it is argued by Appellants that there is no basis for selecting the material of Gore, the conceded prior use of PTFE and expanded PTFE in medical balloons (Spec. 1) contradicts this argument. Prior use in the field of endeavor would appear to provide strong evidence that a material is a known substitute. It is unclear how the use of expanded PTFE in medical balloon devices can generally be conceded to be known from the prior art (Spec. 1), but be asserted to be nonobvious as a substitute for use in *this* balloon (of Crocker), as Appellants appear to argue.

Appellants' Argument:

Appellants argue that even after *KSR*, there must be some motivation to substitute the Gore material for those disclosed in Crocker (Supp. Br. 8). Appellants further argue that one must be able to readily recognize a benefit of modifying the balloon with the porous PTFE of Gore, and if one cannot implement a predictable variation, the combination does not preclude patentability (*Id.*).

Art Unit: 1791

Response:

After *KSR*, other rationale for combining references are no longer foreclosed. The particular motivation does not control the inquiry. *KSR*, 82 USPQ2d at 1397. What matters is the objective reach of the claim. *Id.* Appellants do not argue that there is any difference between the claimed invention and the Crocker reference applied in the rejection above except that Appellants have substituted one material already conceded to be known for use in balloon medical devices (expanded polytetrafluoroethylene) (Spec. 1) for those suggested in the non-exclusive list of Crocker (col. 5, ll. 32-39). Appellants do not appear to have presented any evidence that modifications necessary to achieve the combination were uniquely challenging or difficult for those in the art, or that they produced any unexpected benefits. Thus, once the background for determining obviousness under 35 U.S.C. 103(a) was established by applying the factual inquiries set forth in *Graham v. John Deere Co.*, and it is was determined that the difference between the prior art and the claims at issue was no more than the simple substitution of one known material for another, no further analysis should have been required. *Ex Parte Smith*, 83 USPQ2d 1509, 1518 (Bd. Pat. App. & Int. 2007) (citing *KSR v. Teleflex*). However, even if a TSM type rationale were required, it is submitted that Crocker's suggestion to use any of a list of materials "and others" (col. 5, ll. 35-39) would additionally motivate one to make the combination set forth in the rejection above.

Appellants' Argument:

Appellants further argue that the rejection is based on hindsight (Supp. Br. 8).

Response:

In *KSR*, the Supreme Court noted that while the factfinder should be aware of the distortion caused by hindsight bias and cautious of arguments reliant upon *ex post* reasoning, it is unnecessary and inconsistent with the case law to apply a rigid preventative rule that would deny factfinders recourse to common sense. *KSR*, 82 USPQ2d at 1397. The Examiner's position is that Crocker's teaching to use any of a variety of non-distensible materials "and others" (col. 5, ll. 28-39) suggests incorporation of other materials. To select another substitute material disclosed by Gore and which Appellants concede is already known for use in balloon devices (Spec. 1) is not the work of hindsight bias.

Appellants' Argument:

Claim 23 is not obvious over the combination of Crocker and Gore for at least the reasons that claim 18 is not obvious over the same combination. There is no apparent benefit to selecting the PTFE disclosed by Gore as a substitute for the nondistensible materials disclosed by Crocker.

Response:

If it is found to be obvious to substitute the material of Gore for that of Crocker and that this combination renders obvious the subject matter of Claim 18, then Claim 23 should also be obvious because it requires substantially the same combination of limitations. Gore expressly suggests that the porous structure produced by that reference is useful for laminating and bonding with other materials to provide composite structures (col. 1, ll. 37-41).

Art Unit: 1791

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Matthew J. Daniels/

Patent Examiner, Art Unit 1791

Conferees:

Yogendra Gupta

/Yogendra N Gupta/

Supervisory Patent Examiner, Art Unit 1791

/Steven P. Griffin/

Supervisory Patent Examiner, Art Unit 1791